



Additional information, including a video, is available at ARIKAYCE.com



ARIKAYCE[®]
(amikacin liposome
inhalation suspension)

Limited
Population*

ARIKAYCE Quick Start Guide

Lamira[®] Nebulizer System for ARIKAYCE[®]

Before using your Lamira Nebulizer System, please be sure you read and understand the detailed information in the full Instructions for Use that comes with the Lamira Nebulizer System.

If you do not understand any part of the instructions, contact **inLighten™ Patient Support 1-833-LIGHT-00 (1-833-544-4800)** before using the Lamira Nebulizer System.

*See the full prescribing information for ARIKAYCE for information about the limited population.



1-833-LIGHT-00 (1-833-544-4800)

A. Getting Started

Store your ARIKAYCE medicine refrigerated until expiration date on vial. Do not freeze.

1 Gather your ARIKAYCE medicine. The ARIKAYCE 28-day kit contains:

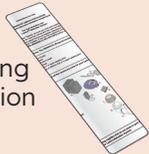
1 Quick Start Guide



1 Instructions for Use insert



1 Full Prescribing Information insert



1 Lamira Nebulizer Handset



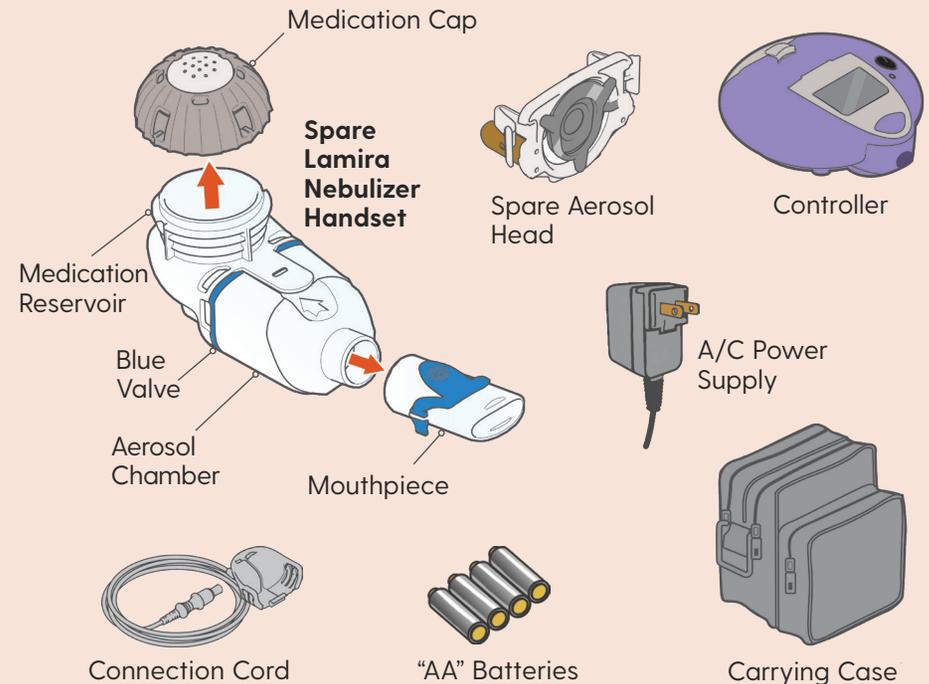
28 vials (1 vial each day) of ARIKAYCE (7 in each weekly box)

4 Lamira Aerosol Heads (1 in each weekly box)



Inside the Weekly Box (4 weekly boxes in each kit)

2 Check to make sure you have all the necessary parts for your Lamira[®] Nebulizer System.



3 You will also need the following supplies:

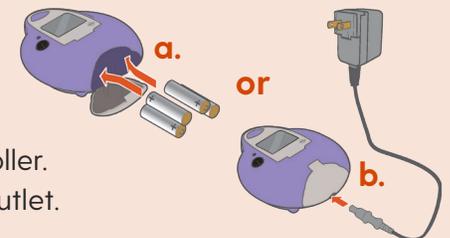
- Clear liquid soap for cleaning the Handset and Aerosol Head
- Distilled water for disinfecting the Handset and Aerosol Head

4 Choose your power supply and get it ready.

- 4 "AA" batteries **or**
- A/C Power Supply

- Plug the A/C Power Supply into the Controller.
- Plug the A/C Power Supply into the wall outlet.

Do not insert the A/C Power into the front of the Controller.



B. One Time Step Before First Use: Cleaning and Disinfecting Your Handset and Aerosol Head



Clean and disinfect your Handset and Aerosol Head before the first use.

When you receive your Handset and Aerosol Head, they will not be sterile. Cleaning and disinfecting your Handset and Aerosol Head is important to reduce the risk of infection, illness, and contamination.

1 Cleaning the Handset and Aerosol Head Before First Use

Reminder: Clean the Handset and Aerosol Head before first use.

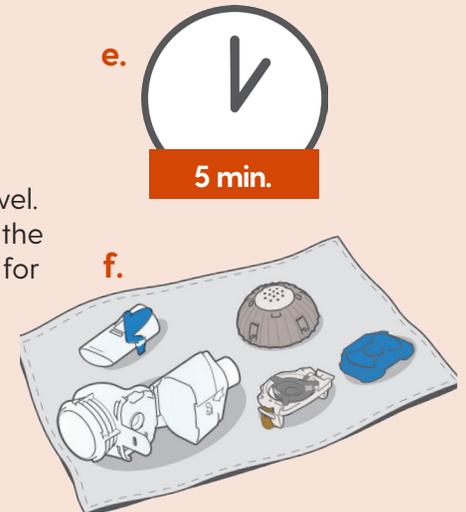
- a. Take apart (disassemble) the Handset for cleaning.
- b. Rinse each of the parts under warm running tap water for **10 seconds**. Rinse the Aerosol Head for **10 seconds on each side**.
- c. Clean all Handset parts by adding a few drops of clear liquid dish soap and warm tap water to a clean tub or bowl. Cover the Handset parts in the warm soapy water and soak for **5 minutes**, shaking them periodically. Then rinse them thoroughly under warm running tap water.



2 Disinfecting the Handset and Aerosol Head Before First Use

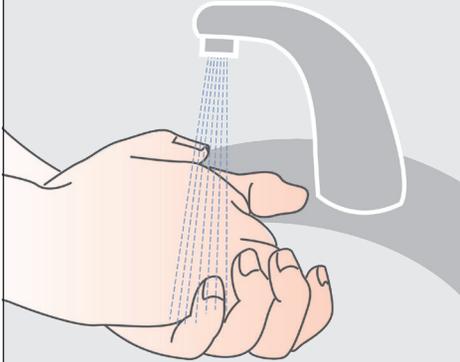
Reminder: Disinfect the Handset and Aerosol Head before first use.

- a. Be sure your Handset and Aerosol Head are clean before you disinfect.
- b. Make sure the pot has enough distilled water to completely cover all the Handset parts including the Aerosol Head.
- c. Heat the water to a boil in a clean pot.
- d. Place the Handset parts, including the Aerosol Head, into the boiling water.
- e. Boil for a full **5 minutes**. Note: It may be helpful to use a timer.
- f. Air dry on a **lint-free** towel. When fully dry, wrap up the parts in a lint-free towel for storage. You can put them together again just before taking your next treatment.



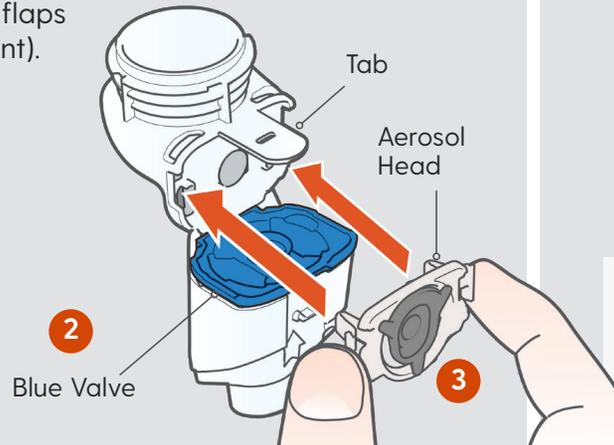
C. Assembling Your Handset

- 1 Wash your hands with soap and water, and dry them well.



- 2 Insert the Blue Valve.

- Open the Handset by gently pulling up on the tab of the Medication Reservoir.
- Insert the Blue Valve so that it rests on top of the Aerosol Chamber with the 2 valve flaps facing down (valve flaps not bent).



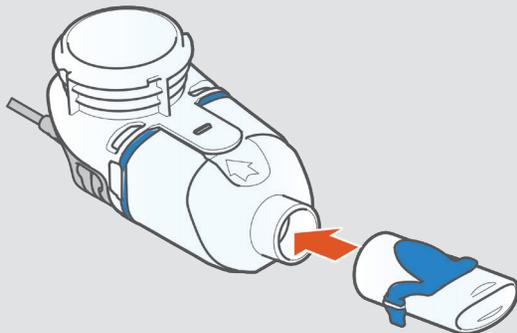
- 3 Insert the Aerosol Head.

- Grasp the Aerosol Head by the 2 flexible plastic tabs on each side. Be sure the text "Lamira®" is facing toward you and is at the top of the Aerosol Head.
- Squeeze the 2 flexible plastic tabs together while inserting the Aerosol Head into the Medication Reservoir.
- Close the Handset when you are done (no gaps along blue valve edge).

Do not touch the silver part of the Aerosol Head at any time.

After the Aerosol Head has been used 7 times, throw away (dispose of) and replace with a new one during the cleaning process. Lamira Handset is to be used for 28 days.

- 4 Attach the Mouthpiece to your Handset with the Blue Flap facing up.

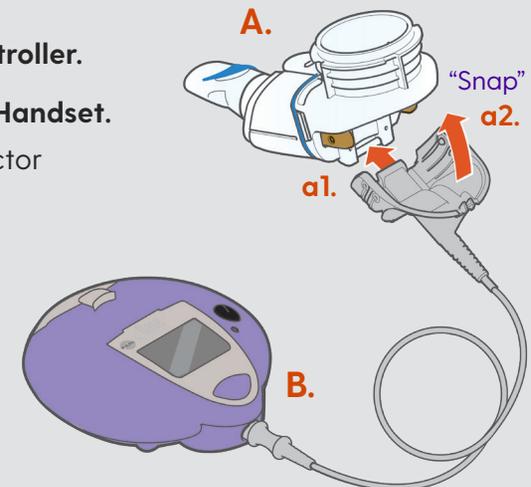


- 5 Finally, attach the Handset to the Controller.

A. Attach the Connection Cord to the Handset.

- a1. Line up the bottom of the Connector with the bottom of the Handset.
- a2. Push upward against the Handset until you hear the pieces snap together.

B. Connect the Connection Cord to the Controller.



D. Taking ARIKAYCE

Your ARIKAYCE should be at room temperature before use to make sure that your Lamira Nebulizer System operates properly. **Do not use other medicines in your Handset.**

Bring ARIKAYCE to room temperature by removing it from the refrigerator at least 45 minutes before use. **Do not use if your ARIKAYCE has been frozen.**

1 Get your ARIKAYCE ready.

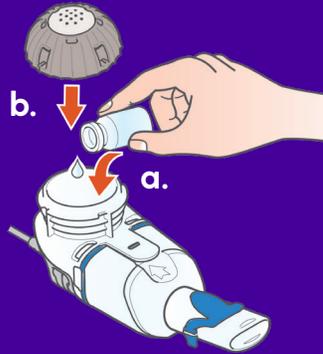
- Place the Handset on a clean, flat, stable surface.
- Shake the ARIKAYCE vial well for **a minimum of 10 to 15 seconds, AND UNTIL THE MEDICINE LOOKS THE SAME THROUGHOUT AND WELL MIXED.**

a. Open the vial and pour the ARIKAYCE into the Medication Reservoir. **See instructions for how to open the ARIKAYCE vial on the right** ▶



Shake minimum 10-15 sec.

b. Attach the Medication Cap.



For any issues you may have with your Lamira Nebulizer System, see Section J – Frequently Asked Questions and Section K – Troubleshooting of the full Instructions for Use that comes with your medicine.

How to open the ARIKAYCE vial

a. Lift the orange cap from the vial.



b. Grip the metal ring on top of the vial and pull it down gently until 1 side breaks away from the vial but do not pull the tab completely off.



c. Pull the metal band from around the vial top in a circular motion until it comes off completely.

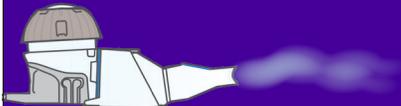


d. Carefully remove the rubber stopper.



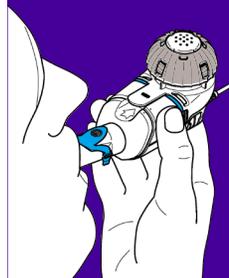
2 Sit in a relaxed, upright position.

- Press and hold down on the On/Off button for a few seconds to turn the Lamira® on.
- Mist will begin to flow.



3 Insert the Mouthpiece (but do not cover the blue flap) and take slow, deep breaths.

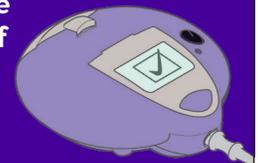
- Then, breathe normally in and out through the Mouthpiece until your treatment is complete.
- Treatment should take about 14 minutes but could take up to 20 minutes.



Be sure to hold the Handset level throughout the treatment.

4 Check that your treatment has ended.

- The Lamira Nebulizer System will beep 2 times.
- A Checkmark will briefly appear on the screen.
- The Controller will automatically shut off.
- Remove the Medication Cap and **check the Medication Reservoir to make sure that no more than a few drops of ARIKAYCE remains. If ARIKAYCE remains, replace the Medication Cap, press the On/Off button, and complete your dose.**



E. Cleaning Your Lamira Handset and Aerosol Head After Every Use

Cleaning and disinfecting your Handset and Aerosol Head is important to reduce the risk of infection, illness, and contamination.

Immediately after each use, the Handset and Aerosol Head should be rinsed, cleaned, and disinfected.

1 Cleaning the Handset and Aerosol Head

Reminder: Clean the Handset and Aerosol Head immediately after each use.

- Disconnect your Handset from the Connection Cord, then take apart (disassemble) the Handset for cleaning.
- Gently wipe away any drops of medicine** from the Medication Reservoir, Aerosol Chamber, and Mouthpiece before rinsing, to reduce antibiotics added to water systems.

Use only plain, dry paper towels or wipes. Do not use towels or wipes that have any chemicals added to them such as alcohol, lotion, or baby wipes.

Be careful not to harm the parts. Do not wipe Aerosol Head.

Throw away paper towels by disposing in trash with solid waste.

- Rinse each of the parts under warm running tap water for **10 seconds**. Rinse the Aerosol Head for **10 seconds on each side**.



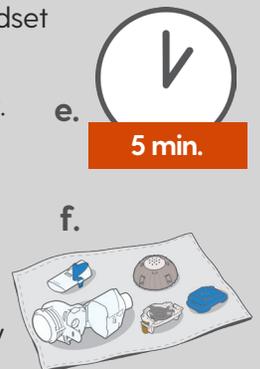
- Clean all Handset parts by adding a few drops of clear liquid dish soap and warm tap water to a clean tub or bowl. Cover the Handset parts in the warm soapy water and soak for **5 minutes**, shaking them periodically. Then rinse them thoroughly under warm running tap water.



2 Disinfecting the Handset and Aerosol Head

Reminder: Disinfect the Handset and Aerosol Head after every use.

- Be sure your Handset is clean before you disinfect.
- Make sure the pot has enough distilled water to completely cover all the Handset parts including the Aerosol Head.
- Heat the water to a boil in a clean pot.
- Place the Handset parts, including the Aerosol Head, into the boiling water.
- Boil for a full **5 minutes**. Note: It may be helpful to use a timer.
- Air dry on a **lint-free** towel. When fully dry, wrap up the parts in a lint-free towel for storage. You can put them together again just before taking your next treatment.



3 Cleaning Your Controller and Connection Cord

- To reduce the risk of electric shock, disconnect all connections before cleaning.**
- Clean the Controller housing and Connection Cord as needed with a soft, clean, damp cloth.
Do not place the Controller unit under water. Do not allow liquid or moisture to get inside the Controller.

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